

REMARKS/ARGUMENTS

I. NON-PRIOR ART MATTERS.

- A. The Office Action rejected claims 1 and 4-6 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Appropriate amendments have been made. These amendments do not create new matter, as they are fully supported in the Specification and drawings as originally filed.

II. PRIOR ART MATTERS.

- B. The Office Action rejected claims 1 and 4-6 under 35 USC 103(a) as being unpatentable over Caspers '709 in view of Norvell. Applicant respectfully traverses the rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.¹ If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness.²

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.³

Applicant respectfully traverses the § 103 rejection because the office action has not established a *prima facie* case of obviousness.

4/15 Le Doe) First, Caspers '709 does not teach a vacuum source connected to a space between the liner and residual limb to lower the partial water vapor pressure in the space.

¹ MPEP Sec. 2142

² Id.

³ Id. (emphasis supplied)

Careful examination of the Figures in conjunction with the Specification of Caspers '709 will show that vacuum is applied to the space 62 between the liner 92 and the socket, but not between the liner 92 and the limb 14. The Specification teaches, at col. 6 lines 41-49:

The hypobarically-controlled artificial limb 50 may also include a nonfoamed, nonporous polyurethane liner 92 receiving the residual limb 14 and disposed between the sheath 90 and the residual limb 14. **The liner 92 provides a total-contact hypobaric suction, equal weight distribution socket liner. The liner 92 readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14.**

Thus, it is impossible in Caspers '709 for vacuum applied to the space 62 to also apply between the limb 14 and liner 92, because the liner 92 tacks up to the limb 14 and would not allow vacuum between it and the limb 14.

Norvell also does not teach this limitation.

In addition, Norvell teaches away from the use of a separate osmotic membrane between a liner and the limb, at Col. 2 lines 41-44:

For example, when inserted into a tight fitting silicone sleeve regularly worn between the wearer and the prosthesis, the bunching of the PTFE material around the side of the limb can lead to chafing and masceration.

This statement would have led one of ordinary skill in the art away from the claimed construction of a separate osmotic membrane between the liner and the limb.

The Examiner is also taking Official Notice that:

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the artificial limb disclosed by Caspers '709 by substituting the liner 92 with the osmotic membrane liner taught by Norvell '169 in order to wick perspiration away from the limb providing extra comfort to the wearer.

This is impermissible. As noted above, the prior art "must teach or suggest all the claim limitations." The Examiner has not shown where the prior art teaches or suggests this modification. In fact, the prior art teaches away from making the combination, as discussed above.

NO

Furthermore, the Examiner has not considered evidence in the Specification supporting the patentability of this claim.⁴ MPEP states:

If the examiner determines there is factual support for rejecting the claimed invention under 35 USC 103, the examiner must then consider evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a preponderance of the evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. The legal standard of "a preponderance of the evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under 35 USC 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

Caspers '709 does not teach the limitation of "a means to maintain a vacuum in the first space and the second space, in the presence of some air leakage past the seal means."

At page 4 of the Specification, Applicant states:

U.S. Patent No. 5,549,709 discloses several embodiments of a hypobarically-controlled artificial limb. However, all of these embodiments required two sockets: an outer socket and an inner socket. Applicant has found that the present invention offers improved performance without the requirement for two sockets. A single socket works equally well or better than two sockets. Also, this patent does not disclose a mechanism for maintaining vacuum in the presence of air leakage into the socket.

Applicant pointed this out to the Examiner in the Amendment and Response filed January 22, 2003 at page 6. The Examiner has not properly considered or weighed Applicant's evidence against the rejection. There is no discussion in the Final Office Action of how the Examiner's statements satisfy the burden of showing a preponderance of the evidence.

Finally, the Examiner has not applied the test of *Graham v. John Deere Co.*⁵ The MPEP requires the Examiner to do so.⁶ However, the Examiner has made no finding of the


MPEP § 2142

level of ordinary skill in the art.⁷ The Examiner has still not applied this test in the Final Office Action.

For the above reasons, Applicant respectfully requests the allowance of all claims and the issuance of a Notice of Allowance. In the event of an appeal, Applicant firmly believes that the arguments presented above will cause reversal of any finding of obviousness. Considering the importance of the invention to the Applicant and the very real time pressures on the Examiner, Applicant believes it is mutually beneficial to reconsider the findings of the Final Office Action.

Respectfully submitted,

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⁵ 383 U.S. 1 (1966)

⁶ MPEP § 2141

⁷ MPEP § 2141.03